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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-18-0556]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Assisted Reproductive Technology (ART) Program Reporting System to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on May 10, 2018 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of

the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

## Proposed Project

Assisted Reproductive Technology (ART) Program Reporting System  
(OMB No. 0920-0556, expires 7/31/2018) - Revision - National  
Center for Chronic Disease Prevention and Health Promotion  
(NCCDPHP), Centers for Disease Control and Prevention (CDC).

## Background and Brief Description

Section 2(a) of Pub. L. 102-493 (known as the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), 42 U.S.C. 263a-1(a)) requires that each assisted reproductive technology (ART) program shall annually report to the Secretary through the Centers for Disease Control and Prevention: (1) pregnancy success rates achieved by such ART program, and (2) the identity of each embryo laboratory used by such ART program and whether the laboratory is certified or has applied for such certification under the Act. The required information is currently reported by ART programs to CDC as specified in the Assisted Reproductive Technology (ART) Program Reporting System (OMB no. 0920-0556, exp. 7/31/2018). CDC seeks to extend OMB approval for a period of three years. The revised total burden estimate is lower than under the previous approval, due to removal of the burden associated with a one-time system upgrade that was completed under the prior approval. However, some of this burden reduction will be offset by an increase in the

number of ART clinics and cycles reported, due to an increase in the utilization of ART in the United States.

The currently approved program reporting system, also known as the National ART Surveillance System (NASS), includes information about all ART cycles initiated by any of the ART programs in the United States. An ART cycle is considered to begin when a woman begins taking ovarian stimulatory drugs or starts ovarian monitoring with the intent of having embryos transferred; for each cycle, CDC collects information about the pregnancy outcome, as well as a number of data items deemed by experts in the field to be important to explain variability in success rates across ART programs and individuals.

Each ART program reports its annual ART cycle data to CDC in mid-December. The annual data reporting consists of information about all ART cycles that were initiated in the previous calendar year. For example, the December 2017 reports described ART cycles that were initiated between January 1, 2016, and December 31, 2016. Data elements and definitions currently in use reflect CDC's prior consultations with representatives of the Society for Assisted Reproductive Technology (SART), the American Society for Reproductive Medicine, and RESOLVE: the National Infertility Association (a national, nonprofit consumer organization), as well as a variety of individuals with expertise and interest in this field.

The estimated number of respondents (ART programs or clinics) is 464, based on the number of clinics that provided information in 2015; the estimated average number of responses (ART cycles) per respondent is 350. Additionally, approximately 5-10% of responding clinics will be randomly selected each year to participate in data validation and quality control activities; an estimated 35 clinics will be selected to report validation data on 70 cycles each on average. Finally, respondents may provide feedback to CDC about the usability and utility of the reporting system. The option to participate in the feedback survey is presented to respondents when they complete their required data submission. Participation in the feedback survey is voluntary and is not required by the FCSRCA. CDC estimates that 75% of ART programs will participate in the feedback survey.

The collection of ART cycle information allows CDC to publish an annual report to Congress as specified by the FCSRCA and to provide information needed by consumers. OMB approval is requested for three years. The estimated annualized Burden Hours are 114,631 which is a decrease of 1,794 from the current OMB-approved collection. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
ART Clinics	NASS	464	350	42/60
	Data Validation	35	70	23/60
	Feedback Survey	348	1	2/60

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